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| 10/582,832 | 03/26/2007 | Yilmaz Niyaz | 65752(45107) | 4961 |
| 21874 7590 06/22/2009 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205 | | | | |
| EXAMINER | | | | |
| FERNANDEZ, SUSAN EMILY | | | | |
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| 1651 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/582,832

Applicant(s)

NIYAZ ET AL.

Examiner

SUSAN E. FERNANDEZ

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 31-61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date 6/14/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

The preliminary amendment filed June 14, 2006, has been received and entered.

Claims 1-30 are cancelled. Claims 31-61 are new.

Claims 31-61 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is indefinite because it is unclear how the "lid portion for covering a container" relates to the other components of the receiving element. Parent claim 38 does not speak of any container, and it is unclear how the container fits in with the receiving surface. Thus, claims 49-52 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-40, 42-47, 49, and 51-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutze et al. (US 5,998,129) in view of Liotta et al. (US 6,251,467).

Schutze et al. discloses a process for sorting and harvesting biological objects on a planar carrier (abstract). For the selection and separation process, an object field of the carrier foil on which the selected biological object or the histological dissection is disposed, is cut out with a laser beam and transferred by a laser induced transport process to a collecting substrate which is directly above or below the carrier foil (column 3, lines 9-15). Furthermore, the carrier foil with the objects to be sorted and the collector substrate are housed in a closed container that has a UV transparent window for the laser beam (column 4, lines 20-23). The cut out area is propelled from the carrier foil onto the adhesive coated collector substrate by a laser induced transport physical process (column 5, lines 25-28). The collector substrate may be a conventional micro titration plate (column 5, lines 28-30).

Schutze et al. differs from the claimed invention in that it does not expressly disclose that the adhesive agent of the collector substrate (the receiving element) is dissolvable without impairing the suitability of the specimen for predetermined processing and/or analysis.

Liotta et al. discloses a method with the following steps: providing a tissue sample, contacting the tissue sample with a selectively activatable surface which can be activated to provide selective regions thereof with adhesive properties, identifying at least one portion of the tissue sample which is to be extracted, selectively activating a region of the transfer surface so that the activated region selectively adheres to the at least one portion of the tissue sample, and separating the transfer surface from the tissue sample while maintaining the adhesion between the activated region of the transfer surface and the at least one portion of the tissue sample (column 3, lines 22-41). In such a process, the sample tissue can be fixed to a glass slide with an agarose gel (column 4, lines 46-49 and column 8, lines 30-33). Note further that the activatable adhesive layer can be made of thermal sensitive adhesives and waxes, hot glues and sealants, ultraviolet sensitive or curing optical adhesives, and thermal or optical emulsions (column 9, lines 52-62). Furthermore, the activatable adhesive layer can be of a wide variety of electromagnetically or thermally activatable materials (column 12, lines 9-10). Also, the activatable adhesive layer is characterized by its ability to be stimulated by electromagnetic radiation so as to become locally adherent to the tissue (column 9, line 65 through column 10, line 1). Infrared absorbing dyes may be added to the activatable adhesive layer to provide strong absorption at other specific infrared wavelengths without altering the films transparency to visible light (column 12, lines 60-63). The tissue specimen placed on the agarose (activatable adhesive layer) can be treated with agents to denature or inhibit RNase in order to perform

mRNA analysis (column 8, lines 53-55). Finally, the Liotta invention allows for recovery and analysis of both active enzymes and mRNA of a sample (column 8, lines 19-21) and for transporting the extracted regions to an automated analyzer which can perform automated analysis of the extracted regions (column 6, lines 23-30).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used the activatable adhesive layer taught in Liotta et al. as the adhesive agent of the Schutze invention. One of ordinary skill in the art would have been motivated to do this because the activatable adhesive layers taught in Liotta et al. are known adhesive agents. Furthermore, they allow for recovery of extracted regions for automated analysis. Since the activatable adhesive layers of Liotta et al. can be stimulated by electromagnetic radiation to become locally adherent, and permit automated analysis following extraction, the activatable adhesive layers of Liotta et al. are adhesive agents that are dissolvable without impairing the suitability of the specimen for predetermined processing and/or analysis. Thus, the following instant claims are rendered obvious: 31-33, 34 (the infrared absorbing dyes can be included in the activatable adhesive layer, which are considered agents for processing, wherein the processing is the selection of a tissue sample for analysis), 35, 36 (since agarose can be the activatable adhesive layer), 37 (agents to denature or inhibit RNase can be added to tissue specimen placed on agarose), 38 (agarose is a known hydrogel), 39 (since agarose can be the activatable adhesive layer), 40, 42, 43 (agents to denature or inhibit RNase can be added to tissue specimen placed on agarose), 44, 45 (agarose itself can be considered a cell culture medium), 46, 47, 49 (Schutze invention is in a closed container), 52-56, 57 (the infrared absorbing dyes can be included in the activatable adhesive layer, which are considered agents for processing, wherein

the processing is the selection of a tissue sample for analysis), 58, 59 (agarose is a known hydrogel), 60 (agarose), and 61.

With respect to instant claim 51, the selection of a suitable supporting element height would have been a matter of routine optimization on the part of the skilled artisan. Thus, instant claim 51 is rendered obvious.

A holding of obviousness is clearly required.

Claims 31-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutze et al. and Liotta et al. as applied to claims 31-40, 42-47, 49, and 51-61 above, and further in view of Walthall et al. (US 4,902,295), Akiyoshi et al. (US 4,870,005), Caldwell et al. (US 6,284,503), and Oldenburg et al. (US 6,027,695).

As discussed above, Schutze et al. and Liotta et al. render claims 31-40, 42-47, 49, and 51-61 obvious. However, they do not expressly disclose that the adhesive layer, such as agarose, is dissolvable by addition of an enzyme.

Walthall et al. discloses that agarose polymers can be dissolved by treatment with an agarase solution. Therefore, given that the adhesive layer of the invention rendered obvious by Schutze et al. and Liotta et al. can be agarose, the references indeed teach an adhesive layer that is dissolvable by addition of an enzyme (agarase). Thus, instant claim 41 is rendered obvious.

The references also differ from the claimed invention in that they do not disclose that the hydrogel is based on collagen or polyacrylamide.

Akiyoshi et al. teaches an adhesive layer that can be comprised of agarose or polyacrylamide (column 8, lines 53-55).

Caldwell et al. teaches that collagen can adhere to many cell types (column 9, lines 30-31).

At the time the invention was made, it would have been obvious to have used an adhesive layer of polyacrylamide or collagen in the invention rendered obvious by Schutze et al. and Liotta et al. One of ordinary skill in the art would have been motivated to do this since polyacrylamide and collagen are both adhesive materials. Thus, instant claim 48 is rendered obvious.

Finally, the references differ from the claimed invention in that they do not expressly disclose that the supporting element (microtiter plate) is made of silicone or acrylic polymer.

Oldenburg et al. teaches that microtiter plates can be formed from a highly reflective material, such as acrylic, so as to enhance the performance of the microtiter plate when used for measurement of luminescence (column 8, lines 30-35).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used acrylic polymer as the material for the supporting element (microtiter plate). One of ordinary skill in the art would have been motivated to do this since acrylic polymer is suitable material for microtiter plates. Thus, instant claim 50 is rendered obvious.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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